

August 19, 2004

Gail M. Garvin
Global Environmental, Health & Safety Specialist
Dow AgroSciences LLC
9330 Zionsville Road
Indianapolis, IN 46268

Dear Ms. Garvin:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 3,4,5,6-tetrachloro-2-pyridinecarbonitrile posted on the ChemRTK HPV Challenge Program Web site on February 10, 2004. I commend Dow AgroSciences LLC for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA has reviewed this submission and has reached the following conclusions:

1. Analog Justification. The Test Plan does not adequately support the proposal to use 2,3,4,5,6-pentachloropyridine as a surrogate for 3,4,5,6-tetrachloro-2-pyridinecarbonitrile for physicochemical properties, environmental fate, mammalian toxicity and ecotoxicity endpoints for the purposes of the HPV Challenge Program. For health effects, the impact of a 2-chloro vs. a 2-cyano substituent is unclear. Simply asserting that the toxicity data from the analog apply to the nitrile is insufficient. The submitter needs to compare such factors as the physicochemical characteristics, metabolism and available mammalian toxicity data for the two chemicals. For ecotoxicity, the use of analog data may be plausible, but the submitter needs to provide an adequate rationale, such as similarity of physicochemical properties.
2. Physicochemical Properties and Environmental Fate. As a rule, physicochemical and fate data on analogs are not acceptable for the purposes of the HPV Challenge Program. The submitter needs to provide measured data for physicochemical properties, stability in water, and ready biodegradation for 3,4,5,6-tetrachloro-2-pyridinecarbonitrile.
3. Health Effects. The submitter claims the sponsored chemical is a closed system intermediate (CSI) and thus eligible for reduced testing in the HPV Challenge Program. The Guidance for Testing Closed System Intermediates at <http://www.epa.gov/chemrtk/guidocs.htm> allows for a reduced testing protocol for the Challenge Program if certain criteria are met.

The information provided by the submitter does not satisfy the requirements for CSI classification and eligibility for reduced testing in the HPV Challenge Program for a number of reasons: (1) the manufacturing process is not described in sufficient detail to substantiate the claim that the process is closed; (2) the test plan indicates that this chemical is "typically" not found in downstream products and there is "essentially no potential for environmental exposure"; however, no monitoring data are included to show no detection of the subject chemical in any medium, and no basis is provided for believing that the chemical is not released during manufacture, processing, and consumption and that exposure to the chemical does not occur; (3) no evidence is provided to substantiate that the chemical is not present in other end-products.

Unless additional information is provided to support the CSI claim, the submitter needs to address all health effects endpoints for the purposes of the HPV Challenge Program.

4. Ecological Effects. EPA reserves judgement on the fish endpoint pending receipt of more detailed

information on the submitted studies and an adequate analog justification. Details missing from the submitted fish robust summaries include concentrations tested, use of controls, mortality and effects per concentration, number of animals used per concentration, control response, and the water chemistry parameters. For the invertebrate endpoint, the submitted data are not adequate because the summary lacked details and was conducted using a species not recommended by OECD TG 202. The algal endpoint is not adequately addressed since no robust summary was provided. Therefore, the submitter needs to address the invertebrate and algal endpoints by providing adequate measured data.

EPA will post this letter on the HPV Challenge Web site within the next few days. We ask that Dow AgroSciences advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Dr. Ralph Northrop, of the HPV Chemicals Branch, at 202-564-7666. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

/s/

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber